8

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/742,520	12/20/2000	Ilham Saleh Abuljadayel	674528-2001.2	9656

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EXAMINER	
SAUNDERS, DAVID A	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/742,520	ABULJADAYEL, ILHAM SALEH	
	Examiner	Art Unit	
	David A. Saunders, PhD	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004 and 04 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-52,55,56,61-63,65,66,73 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-52,55,56,61-63,65,66,73 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment of 4/7/05 has been entered. Claims 47-52, 55-56, 61-63, 65-66 and 73-74 are pending and under examination.

The amendment has overcome the following objections/rejections stated in the office action of 4/13/04:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1.) The objection to the specification for containing new matter by virtue of the deletion of text from page 34 in the amendment filed on 5/21/03. The examiner considers that as the terms "high" and "low" are employed in amended claim 47 is consistent with how one in the art would understand these terms and with how they were to be understood elsewhere in the specification.

2.) The objection to claims 57-59 under 37 CFR 1.75 (c).

3.) The rejection of claims 47-72 under 112, 2nd para.

4.) The 112, first para. rejection of claim 53 for containing new matter.

5.) The 112, first para. rejection of claims 67-72 for containing new matter.

6.) The 112, first paragraph rejection of claims 63-65 for lack of possession of the genus of biological response modifiers.

7.) The 112, first paragraph rejection of claim 63 for scope of enablement.

8.) The 101/112 utility/how to use rejection. It is deemed that since the specification shows that the observed increase in the proportion of CD34+ cells (as in the claims of Pat. 6,090,625) are correlated with an increase in the proportion of CD45 low cells, that a showing of utility for the former is a showing of utility for the latter.

While there might be some yet undiscovered special utility for the CD45 low population that would differ from that for the CD34+ population, it is not considered that applicant must have known and disclosed this special utility; a showing of one utility is sufficient. See In re Malachowski 189 USPQ 432.

The following rejections of record are maintained:

Claims 47-52, 55-56, 61-63, 65-66 and 73-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. One cannot envision the subgenus of antibodies against MHC class I and class II antigens that have the functional property of increasing the relative number of CD 45 low cells compared to the number of CD 45 high cells.

Claims 47-52, 55-56, 61-63, 65-66 and 73-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of antibodies against MHC class I or class II antigens which bind to the alpha or beta chains thereof, does not reasonably provide enablement for the use of antibodies that bind to any other components/chains of MHC class I or class II antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. In addition to the alpha and beta chain components of MHC class I and II antigens. There are other chains. For example; there is a beta-2-microglobulin associated with

MHC-class I and an invariant chain associated with MHC-class II (see Cruse et al at page(s) 35 and 173).

Since these are not the same chains that were bound (or "engaged") by the antibodies exemplified, one would have no reason to expect that, when one binds an antibody to these other chains, there would be the same functional effect of increasing the relative number of CD 45 low cells; applicant's urgings of 10/12/04 have been considered but are unconvincing.

Claims 47-52, 55-56, 61-63, 65-66 and 73-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,090,625. Although the conflicting claims are not identical, they are not patentably distinct from each other because the "contacting" and "incubating" steps of instant claim 47 and issued claim 1 use the same agent -- i.e. an antibody to the MHC class I or class II antigen, when one reads issued claim 1 as containing the limitation of issued claims 3-4 and 10-12. It is therefore considered that the "contacting" and "incubating" steps of both sets of claims inherently accomplish the same result, whether that result is recited as increasing the relative number of CD 45 low cells (as instantly) or of CD 34+ cells (as in issued claim 1). It is noted that applicant's response of 5/21/03 has considered that CD34+ cells are CD45 low; this urging shows that instant claim 47 and the issued claims would encompass common embodiments.

With respect to the "determining" step of claim 47, this does not distinguish over issued claim 1. Such determining, prior to conducting a process would have been

conventional and obvious, so that one conducting the process would have a base line against which one could determine whether any increase had occurred in the subsequent steps.

It is noted applicant would file a disclaimer, once allowable subject matter is indicated.

Applicant's amendment has necessitated the following new ground(s) of rejection:

Claims 48, 50-52, 56 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 48 "engaging a receptor by direct or indirect engagement" is unclear. The "receptor" has no clear relationship to the components recited in base claim 47. If this "receptor" is intended to be the same as the previously recited MHC class I or class II antigen, then it is unclear what is meant by "direct" or "indirect engagement." Note that an antibody to an MHC antigen binds to that antigen in a "direct" manner, not in an "indirect" manner. It is therefore meaningless to recite "indirect" and redundant to recite "direct".

In claims 50-52 and 66 "the committed cells" lack antecedent basis.

In claim 56 "the MHC class I antigen is an HLA-DR receptor" is confusing, because claim 55 has correctly recited that an "HLA-DR receptor" is a "class II antigen".

Any response to this FINAL rejection must include a terminal disclaimer.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Monday-Thursday from 8:00a.m to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182

Saunders/tgd
June 13, 2005